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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	C-3320/1/US	5208

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,494	LE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 11/17/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Straub et al. US 6,395,300.

Mizumoto teaches a quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The blending ratio of high moldability and low moldability saccharides is from 2 to 20% by weight (column 7, lines 3-18). Drug is used in an amount of about 50% (column 10, lines 25-26). Drug includes both analgesic and anti-inflammatory agents (column 7, lines 13-15 and 39-41). The method for preparing the tablet is disclosed in columns 12-13 (see also examples). The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed at column 11, lines 30-60.

Mizumoto does not expressly teach the claimed surfactant, as well as the claimed active agent such as celecoxib. However, celecoxib is a well-known non-steroidal anti-inflammatory. To be more specific, Straub is cited for the teaching of non-steroidal anti-inflammatory drug includes celecoxib (column 4, lines 55-58). Straub further teaches processing celecoxib with excipient such as wetting agent or surfactant into tablet suitable for oral administration (column 3, lines 5-6; and column 8, lines 10-14). Wetting agent or surfactant includes fatty acid ester, polyoxyethylene alkyl ether, sodium lauryl sulfate, silicon dioxide, and combination of two or more (column 9, lines 3-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto using the wetting agent in view of the teaching of Straub to obtain the claimed invention, because Straub teaches wetting agents (surfactants) are well known pharmaceutical excipients (column 9, lines 25-26), because Straub teaches the use of wetting agent to facilitate dissolution, because Straub teaches the use of stearic acid, or polyethylene glycol as a wetting agent, because Straub teaches the non-steroidal anti-inflammatory such as ibuprofen, ketoprofen, flurbiprofen, and celecoxib, because Mizumoto teaches the use of stearic acid, polyethylene glycol *and the like* (column 13, lines 52-53), and because Mizumoto teaches non-steroidal anti-inflammatory such as ibuprofen, ketoprofen, flurbiprofen *and the like* (column 8, lines 13-15).

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Straub et al. US 6,395,300 and Jain et al. US 6,316,029.

Mizumoto is relied upon for the reason stated above. Mizumoto does not expressly teach the claimed active agent such as celecoxib. However, celecoxib is a well-known non-steroidal anti-inflammatory. See Straub at column 4, lines 55-58, discloses non-steroidal anti-inflammatory drug includes celecoxib.

It is further noted that Mizumoto does not teach the claimed surfactant.

Jain teaches a process for preparing rapidly disintegrating solid oral dosage form, wherein the rapidly disintegrating dosage form comprises surfactant including sodium lauryl sulfate, and one or more pharmaceutical excipients such as silicon dioxide (column 7, lines 15-67; and column 8, lines 59-64). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto using the surfactant in view of the teaching of Jain to prepare a quick-dissolved formulation, because Jain teaches the use of surfactant as excipient in a quick disintegrating tablet is well known pharmaceutical art (column 7, lines 2-33; and column 8, lines 14-18). The expected result would be a compressed tablet having good hardness, and dissolved quickly upon contact with fluid.

The examiner notes that the cited references are silent as to the claimed amounts of glidant, and wetting agent in claims 18-20 and 23-25. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 11/17/05 have been fully considered but they are not persuasive.

Applicant argues that the claims as amended require adding a surfactant, and therefore, the cited references do not teach the claimed surfactant. In response to applicant's argument, Mizumoto is cited in view of Straub or Jain for the teaching of the amended claims.

Applicant argues that there is no motivation to combine Mizumoto and Jain because nothing in Jain suggests the need for formulating their poorly soluble drug and surface stabilizer with the saccharide having low moldability and the saccharide having high moldability required by Mizumoto. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Mizumoto teaches the use of tabletting additives, such as lubricant including stearic acid, polyethylene glycol, and silicon dioxide. Jain teaches surfactant includes the claimed surfactant, as well as stearic acid, polyethylene glycol, and silicon dioxide. Accordingly, Jain teaches the equivalency of these well-known pharmaceutical excipients. Furthermore, the test for obviousness is not whether the

features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

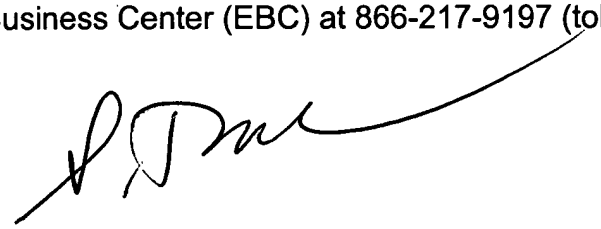
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Tran
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